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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,955	10/28/2003	Robert Naylor Laurie	P07351US01/BAS	3799
881 7590 03/16/2010 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 03/16/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/693,955

**Applicant(s)**

LAURIE ET AL.

**Examiner**

Humera N. Sheikh

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 4, 8, 10, 13 and 15 is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/935,550.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response and Amendment after Non-Final Office Action and Applicant's Arguments/Remarks, all filed 09/01/09 and the Response to Notice of Non-Compliant Amendment filed 01/11/10 is acknowledged.

Applicant has overcome the following rejections by virtue of the amendment to the claim(s) and/or persuasive remarks: (1) The 35 U.S.C. §112, first paragraph rejection of claim 11 has been withdrawn; and (2) The 35 U.S.C. §112, second paragraph rejection of claim 8 has been withdrawn.

Claims 1, 3, 4, 8 and 10-16 are pending in this action. Claims 8 and 11 have been amended. Claims 2, 5-7 and 9 have previously been cancelled. Claims 1, 3, 4, 8, 10, 13 and 15 are allowable. Claims 11, 12, 14 and 16 remain rejected.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 11, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent No. 4,335,116).**

**Howard ('116)** teaches stable mineral-containing therapeutic compositions in the form of aqueous solutions for parenteral administration to domesticated animals, such as livestock. The compositions comprise water-soluble organometallic complexes of ions of zinc, copper, manganese, chromium and selenium and including at least two organic, metal-ion-complexing agents. Methods for restoring and/or maintaining normal micromineral-dependent metabolic function, increasing feed intake, increasing vigor and facilitating resistance to infectious disease comprising administering the solutions to domesticated animals is also disclosed (see Abstract); (col. 4, line 51 – col. 5, line 5).

Solutions may be prepared to provide from about 0.1 to about 25 mg of *zinc*; from about 0.1 to about 10 mg of *copper*; from about 0.1 to about 20 mg of *manganese*; from about 0.01 to about 5.0 mg of *chromium*; and from about 0.1 to about 12.0 mg of *selenium* (col. 5, lines 26-35); (Claim 1). These mineral amounts are equivalent to 72 mg/ml of the combined zinc, copper, manganese, chromium and selenium components. Thus, the “72 mg/ml” metal concentration of Howard reads on Applicant's metal concentration of “60 mg/ml” recited in instant claims 11 and 16.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Howard. Howard explicitly

teaches mineral-containing solutions formulated for domesticated animals (i.e., livestock) whereby the solutions are comprised of various minerals that necessarily include zinc, copper, manganese, chromium and selenium. These minerals are provided in effective amounts to yield a total concentration that is greater than 60 mg/ml as is claimed by Applicant. The solutions are useful for parenteral administration and thus read on the “injectable solution” as claimed.

\* \* \* \* \*

*Response to Arguments*

Applicant's arguments filed 09/01/09 have been fully considered and were found to be partially persuasive.

▪ **Rejection under 35 U.S.C. 112, first paragraph:**

Applicant argued, “Applicants have amended claim 11 to recite that the solution comprises a metal concentration of 60 mg/ml. In reciting that the solution comprises a concentration of 60 mg/ml, using the open-ended language “comprising”, means that the trace metal concentration could be greater than 60 mg/ml.”

Applicant's arguments were found persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claim 11 has been withdrawn.

▪ **Rejection under 35 U.S.C. 112, second paragraph:**

Applicant argued, “The phrase ‘such as’ was deleted thereby rendering the rejection to claim 8 moot.”

Applicant's arguments were found persuasive by virtue of the amendment to claim 8. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claim 8 has been withdrawn.

▪ **Rejection under 35 U.S.C. 103(a) over Howard (US 4,335,116):**

Applicant argued, “Howard fails to provide an enabling disclosure for one of ordinary skill in the art to produce a trace element solution having the alleged 72 mg/ml total metal concentration were one to consider the upper limit of all of the ranges of metal concentrations of claim 1 in Howard. Howard would not have allowed one of ordinary skill in the art to produce the presently claimed 60 mg/ml, let alone 72 mg/ml as alleged by the Examiner. All examples in Howard include a substantially smaller concentration than the 60 mg/ml.”

Applicant’s arguments have been considered but were not found persuasive. The disclosure of Howard is enabling for the production of a trace element solution having a possible 72 mg/ml total metal concentration, since Howard explicitly teaches and suggests suitable and effective ranges for each of the trace elements claimed. Applicant is arguing and emphasizing the preferred embodiments of Howard (at column 5, lines 40-59) and is disregarding the fact that Howard vividly discloses ranges of both low and high amounts of trace elements, whereby one of ordinary skill in the art would choose higher amounts of the trace elements, if so desired. The reference at column 5, lines 26-39, is clearly suggestive of effective ranges, whereby high amounts of the trace elements is taught and therefore, can be used. Moreover, Applicant is also arguing the lower amounts used in the Examples of Howard, namely, Examples 1 and 2. However, the Examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Furthermore, the teachings of the prior art are not limited to the examples disclosed therein. Nonetheless, as delineated above, the reference provides ranges of trace elements whereby the upper limit of the metal concentrations (which total 72 mg/ml) would read on the metal concentrations claimed (60 mg/ml).

Applicant also argued, "The reason why the present invention is capable of producing a product with concentrations as disclosed in the present invention is namely due to the use of a continuous process, as compared to Howard's single product approach, and the relative stabilities of the minerals to be supplied. Most importantly, the present process enables the manufacture of a product comprising higher concentrations than those of Howard, resulting in having the 60 mg/ml trace element solution."

These arguments were not persuasive. Note that the rejected claims are drawn to "product" claims and not process of making claims, nor product-by-process claims. As such, the process by which the product is formed does not impart patentable weight. The claims are merely drawn to an "injectable trace element solution", indicative of product claims. Moreover, Howard recognizes ranges of trace elements, whereby the upper limit claimed would read on the "60 mg/ml" claimed by Applicant.

Applicant argued, "Howard uses tetrasodium EDTA, whereas the present invention uses EDTA and/or disodium EDTA."

This was not persuasive. Note that none of claims 11, 12, 14 or 16 recite any reference to EDTA and/or disodium EDTA. The claims merely claim an "injectable trace element solution", with no mention of EDTA and/or disodium EDTA, as argued by Applicant. Hence, the tetrasodium EDTA of Howard is permissible, given the present claim language.

Applicant argued, “based on the foregoing, Howard fails to anticipate the claimed invention and claims 11, 12, 14 and 16 are not anticipated by Howard.”

The Examiner reminds Applicant that the claims (11, 12, 14 and 16) have been rejected under 35 U.S.C. §103(a) and not under 35 U.S.C. §102. Thus, one of ordinary skill in the art would find the instant invention *prima facie* obvious, at the time the invention was made, based on the teachings of Howard. Howard explicitly teaches and suggests effective ranges for each of the trace elements claimed, including both low and high amounts of trace elements, which would read on the concentration levels as claimed (60 mg/ml).

The Declaration under 37 CFR 1.132 of William Alfred Smith filed 01 September 2009 has been fully considered but is insufficient to overcome the rejection of claims 11, 12, 14 and 16 based upon Howard under 35 U.S.C. §103(a) as set forth in the last Office action. As discussed above, Howard expressly teaches suitable ranges for each of the trace elements claimed whereby the upper limit of the metal concentrations (which total 72 mg/ml) would read on the metal concentrations claimed (60 mg/ml). The reference at column 5, lines 26-39, is clearly suggestive of effective ranges, whereby high amounts of the trace elements is taught and therefore, can be used. Applicant is emphasizing the lower amounts used in the Examples of Howard, namely, Examples 1 and 2. However, the Examiner again points out that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Furthermore, the teachings of the prior art are not limited to the examples disclosed therein. Nonetheless, the upper maximum limits of trace elements provided by Howard would read on the metal concentrations claimed (60 mg/ml). In addition, even if the most upper limits of



Howard were not employed, but rather the intermediate-upper limits were used, there would be some degree of overlap between Howards' trace element composition and that of the present invention, absent a showing of evidence to the contrary. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). The present claims remain generic enough to read on the teachings of the prior art of record discussed above.

This rejection has been maintained.

#### ***Allowable Subject Matter***

Claims 1, 3, 4, 8, 10, 13 and 15 are allowable.

\* \* \* \* \*

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 11, 12, 14 and 16 remain rejected.

Claims 1, 3, 4, 8, 10, 13 and 15 are allowable.

Claims 2, 5-7 and 9 are cancelled.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

*hns*

March 12, 2010

